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| APPLICATION NO. 772 | FILED DATE 16/00 | PETER FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. 145.1339 |
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| EXAMINER SPIEGEL, A |
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| ART UNIT 1656 | PAPER NUMBER |
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DATE MAILED:

10/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/554,772

Applicant(s)

PETIT ET AL.

Examiner

Alexander H. Spiegler

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-6 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-6 and 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No. 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. This action is in response to Paper No. 7, filed on August 2nd, 2001. Currently, claims 3-6 and 8-10 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3-6 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 3-6 and 8-10 are indefinite over the recitation of "arterial thrombotic complications associated with atherosclerosis" because it is not clear as to what is meant by this recitation. (i.e. it is not clear as to what complications are "associated" with atherosclerosis).

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 3-6 and 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Agouridas et al. (USPN 5,747,467).
Agouridas et al. teaches a method of combatting bacterial infections in warm-blooded animals including humans comprising, administering to warm-blooded animals an effective amount of a ketolide or its non-toxic, pharmaceutically acceptable acid addition salts (col. 5, ln. 33-38). With respect to claims 3-6 and 9, the reference teaches a plurality of specific ketolides that can be used in the method in this method of treating warm blooded animals (see whole document). With

respect to claim 10, the reference teaches that the usual daily dose is 1.5 to 6 mg/kg, and therefore, provides a range equivalent to the range provided in claim 10. For example, if the daily dose was at 4mg/kg, and an individual to whom the ketolide was administered weighed 100 kg, then 400 mg would be administered to said individual per day. Furthermore, it is noted that the claims of the instant application are drawn to methods of preventing arterial thrombotic complications associated with atherosclerosis, where the intended use of the method does not carry weight with respect to the novelty or obviousness of the product. Therefore, the recitation "methods of preventing arterial thrombotic complications associated with atherosclerosis" and "to prevent arterial thrombotic complications associated with atherosclerosis" do not distinguish the claimed methods over the methods taught by Agouridas et al. Currently, the claims only recite one active method step (i.e. administering to a warm-blooded animal an effective amount of a ketolide or its non-toxic, pharmaceutically acceptable acid addition salts), which is taught by Agouridas et al.

Conclusion

5. No claims are allowable.

This communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
Alexander H. Spiegler
October 30, 2001

Kenneth R. Horlick, Ph.D.
KENNETH R. HORLICK
PRIMARY EXAMINER 10/30/01
GROUP 1600